IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **WAVE 1 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

DEFENDANTS' MEMORANDUM IN SUPPORT OF MOTION TO LIMIT TESTIMONY OF PROF. DR. MED. UWE KLINGE

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, "Ethicon") submit this memorandum in support of their motion to limit the testimony of Prof. Dr. med. Uwe Klinge. The cases to which this motion applies are identified in Ex. A to the motion.

BACKGROUND

Dr. Klinge is a former hernia surgeon who, when he practiced in his native Germany, used mesh implants in the surgical repair of abdominal wall hernias. Dr. Klinge has been identified as an expert witness in thirty-six cases pending in Wave 1. He offers general opinions about the design of and alternatives to the various meshes manufactured by Ethicon for the treatment of stress urinary incontinence and pelvic organ prolapse.

Dr. Klinge has prepared two Rule 26 expert reports for the Wave 1 cases in which he has been identified as an expert witness.

The first, dated November 16, 2015, concerns the PROLENE* Mesh used in mid-urethral slings manufactured by Ethicon for the treatment of stress urinary incontinence, including the

TVT, TVT-O, and TVT Secur devices. *See* Ex. B, Rule 26 Expert Report of Prof. Dr. Med. Uwe Klinge (Nov. 16, 2015) ("Klinge PROLENE* Report").

Dr. Klinge's second Rule 26 expert report, dated November 17, 2015, relates to the PROLENE* Soft Mesh found in Gynemesh PS, Prolift, and Prosima, each of which Ethicon manufactured for the treatment of pelvic organ prolapse. *See* Ex. C, Rule 26 Expert Report of Prof. Dr. Med. Uwe Klinge (Nov. 17, 2015) ("Klinge PROLENE* Soft Report").

The PROLENE* and PROLENE* Soft meshes are both made of polypropylene treated with antioxidants and share the same chemical structure. But they differ in design. PROLENE* Soft has larger pores, weighs less, and has lower burst strength than PROLENE*. Although Dr. Klinge's opinions regarding PROLENE* and PROLENE* Soft overlap to an extent, the bases underlying his opinions are different, and he has been deposed separately regarding his opinions as to each mesh. Accordingly, this memorandum addresses Dr. Klinge's two expert reports separately, with section I below relating to Dr. Klinge's PROLENE* Report and section II relating to his PROLENE* Soft Report. Challenges that apply to both reports follow section II.

LEGAL STANDARD

Ethicon incorporates by reference the standard of review for *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, 2014 WL 3361923, at *1–3, 2014 U.S. Dist. LEXIS 92316, at *3–8 (S.D. W. Va. July 8, 2014).

ARGUMENT

I. The Court Should Limit Certain of Dr. Klinge's Opinions Regarding PROLENE*.

a. The Court should exclude Dr. Klinge's opinions regarding alternative designs to PROLENE*.

In his PROLENE* expert report, Dr. Klinge identifies two alternative designs that, he claims, "would be safer in a woman's pelvic tissues as a treatment for incontinence than some of the design characteristics of the Prolene mesh in TVT." *See* Ex. B, Klinge PROLENE* Report at 36. Those alternative designs are (1) a device made out of "a mesh product with less material and larger distance between the mesh fibers," such as Ethicon's Ultrapro mesh, which is used in hernia repairs; and (2) a device made of polyvinylidene fluoride ("PVDF") mesh rather than polypropylene. *Id.*

Ultrapro alternative speculative. Dr. Klinge has no reliable basis to testify that a larger pore mesh like Ultrapro would have been safer and efficacious for use in the treatment of stress urinary incontinence. In his expert report, Dr. Klinge does not cite a single clinical study to prove the safety and efficacy of a mid-urethral sling using Ultrapro or a mesh similar to it. Indeed, in the section of his expert report devoted to safer alternative design, Dr. Klinge states only that "a mesh product with less material and larger distance between the mesh fibers" would be safer than PROLENE*. *Id.* He offers no support for this opinion.

Dr. Klinge has acknowledged in deposition that, based on this lack of evidence, he is "not able to predict" whether "in the specific function of a sling the Ultrapro really over the time will work really better or whether it will create some new problems." *See* Ex. D, Klinge 10/5/15 Dep. Tr. 92:17–93:4. He admitted in that same deposition that answering this question would require "preclinical tests," an "independent textile analysis," and an examination of "tissue reactions

looking at animal explants [and] human explants," all of which "should" provide only "a good idea" about whether Ultrapro in a mid-urethral sling is feasible. *Id.* at 94:10–18. These admissions disqualify his testimony, for they admit that he lacks the support in testing and peer-reviewed studies that Federal Rule of Evidence 702 requires. *See Oglesby v. Gen. Motors Corp*., 190 F.3d 244, 249 (4th Cir. 1999) (test data or relevant literature showing testing by others required); *Eghnayem v. Boston Sci. Corp*., 57 F. Supp. 3d 658 (S.D. W. Va. 2014)(flawed testing failed to meet peer-reviewed standards).

More problematic than the lack of reliable evidence is the fact that Dr. Klinge himself doubts whether a mesh like Ultrapro would actually work for the treatment of stress urinary incontinence. He has previously testified in this MDL that Ultrapro is not an appropriate alternative design for the treatment of stress urinary incontinence because it "is not sufficient to withstand—or to preserve the big pores—under these conditions of biomechanics as it is required for the use as a sling." *See* Ex. E, Klinge 11/15/13 Dep. Tr. 529:12–23.

Even today Dr. Klinge has "concerns" that the pores of Ultrapro collapse "at really small forces," and he candidly admitted that he "wouldn't like to have [Ultrapro] in [his] body." *See* Ex. D, Klinge 10/5/15 Dep. Tr. 92:1–3, 93:5–14. Dr. Klinge should not be permitted to testify that a larger pore mesh such as Ultrapro was a feasible alternative design when he has admitted such a design could very well impair the utility of a mid-urethral sling.

PVDF not legally available and speculative. Dr. Klinge's opinion that Ethicon could have and should have employed PVDF mesh when designing the TVT, TVT-O, and TVT Secur should be excluded for the same reason. Dr. Klinge is able to identify only one stress urinary incontinence device in the whole world that uses PVDF: Dynamesh, which is manufactured by

the same German company (FEG) for which Dr. Klinge is a consultant. *See* Ex. D, Klinge 10/5/15 Dep. Tr. 101:2–103:16.

Although Dr. Klinge claims Dynamesh is a feasible alternative design, he acknowledged he does not know whether PVDF mesh is subject to particle loss, nor does he know the "stretching profile" of the device under load. *Id.* at 95:15–24. He has not examined whether PVDF mesh is subject to some of the very same criticisms he levies against PROLENE* Mesh in Ethicon's stress urinary incontinence devices and, therefore, does not have a reliable basis to testify that PVDF mesh was a feasible alternative design available to Ethicon.

Nor can he say whether it would be equally effective for the treatment of stress urinary incontinence.

Moreover, even if Dr. Klinge could reliably testify that PVDF mesh is safer than PROLENE* and efficacious for the treatment of stress urinary incontinence, his opinion would be irrelevant because PVDF mesh does not meet the threshold criteria for qualifying as a safer alternative design. PVDF mesh has not been cleared by the FDA and is not available for use in the United States. *See* Ex. E, Klinge 11/15/13 Dep. Tr. 392:10–393:6.

Dr. Klinge does not cite or rely upon any testing or studies that would show that PVDF could pass the standards imposed by the FDA. The court in *Militrano v. Lederle Labs.*, 769 N.Y.S.2d 839 (N.Y. 2003), explained the perils of speculating that a foreign product not cleared by the FDA could suffice as an alternative design:

> Given that a drug manufacturer cannot market a drug in the United States without FDA approval, for a court to find that an alternative drug should have been developed would require it to predict with confidence that the alternative drug would have actually been approved. No expert could honestly opine that approval would have been granted without engaging in rank speculation.

Id. at 852; *see also Wolfe v. McNeil-PPC, Inc.*, 773 F. Supp. 2d 561, 573 (E.D. Pa. 2011) (observing that if there exists no FDA-approved alternative for the product, "there is no available alternative design of the drug for defendants to adopt").

Further defeating PVDF as a feasible alternative is Dr. Klinge's admission that PVDF mesh is "definitely more expensive" and "more difficult to handle" than the Prolene used in TVT. *See* Ex. E, Klinge 11/15/13 Dep. Tr. 517:15–518:7. As this Court has recognized, "an alternative design is not reasonable if it alters a fundamental and necessary characteristic of the product." *Keffer v. Wyeth*, 791 F. Supp. 2d 539, 549 (S.D. W. Va. 2011) (quoting *Torkie-Tork v. Wyeth*, 739 F. Sup. 2d 895, 900 (E.D. Va. 2010)).

Moreover, an alternative design cannot be "unreasonably expensive." *Dyer v. Danek Med., Inc.*, 115 F. Supp. 2d 732, 738 (N.D. Tex. 2000). Because PVDF mesh fails on both fronts, Dr. Klinge's opinion that it has safer characteristics than PROLENE* Mesh is irrelevant and should be excluded.

b. Dr. Klinge's opinions regarding degradation, fraying, and particle loss in PROLENE* should be excluded.

The Court should also exclude Dr. Klinge's opinion that PROLENE* is defective because it degrades *in vivo* and is subject to fraying and particle loss. *See* Ex. B, Klinge PROLENE* Report at 29–31, 37.

First, this testimony is irrelevant. In the absence of a safer alternative design, the plaintiff can only establish a design defect by showing that the risk of using the TVT product outweighs the utility of the device. Presumably testimony about fraying and particle loss is supposed to go to risk. But an opinion that TVT's risk outweighs its overall utility cannot meet *Daubert* standards because that opinion conflicts with the generally accepted opinion of the medical community, the medical literature, and would be contrary to the opinion of every professional

organization that has spoken on the matter, not to mention the FDA. Therefore, evidence about fraying and particle loss as a design defect is ultimately immaterial.

Second, without expert testimony that the PROLENE* implanted in each plaintiff actually degraded, frayed, and lost particles *in vivo*, the plaintiffs cannot link Dr. Klinge's general opinion to the specific facts of any case, making his opinion irrelevant. *See, e.g., Johnson & Johnson v. Batiste*, No. 05-14-00864-CV, 2015 WL 6751063, at *8 (Tex. App.–Dallas, Nov. 5, 2015) (plaintiff could not show causation where "there is no evidence the mesh that was placed inside Batiste had degraded to the extent that it caused her injury").

Most importantly, Dr. Klinge cannot begin to explain the clinical significance, if any, of these alleged conditions. In his report, Dr. Klinge states that these defects "lead to an increased inflammatory response" that in turn causes complications such as erosions and pain. *Id.* at 3.

Yet he has admitted in deposition that he is not aware of a single clinical study to address the implications of surface degradation. *See* Ex. E, Klinge 11/15/13 Dep. Tr. 516:1–9 ("I don't know any study that was able to differentiate whether [clinical manifestations resulted from] surface cracking, whether it was a surface of the material, whether it was the functional biocompatibility of the device, therefore.").

Similarly, when asked about the effects of fraying and particle loss, Dr. Klinge testified that he does not know of "any clinical study testing the relationship between particle loss and the clinical outcome." *Id.* at 411:12–24; *see also* Ex. F, Klinge 11/4/15 Dep. Tr. 218:23–219:20 (testifying he is not aware of any study showing that fraying leads to clinically significant results).

Not surprisingly, without any data or clinical studies, Dr. Klinge is unable to tie degradation or particle loss in PROLENE* to any specific complication. *See* Ex. E, Klinge

11/15/13 Dep. Tr. 511:1–19 ("My current opinion to this point is that at the moment we don't have sufficient data to quantify exactly the consequence of this finding [of degradation] to the clinical outcome."); *id.* at 416:14–24 ("Q. Prior to this litigation, . . . did you ever identify a potential risk of injury to a patient associated with particles that are lost from a mesh during hernia implantation? A. Only in the sense increased surface generally increases the risks but not specifically that we had some patient with a specific complication that can be related to particle loss, no.").

Dr. Klinge instead opines in his report more generally that these defects cause inflammation and chronic foreign body response. But he cannot reliably link inflammation and chronic foreign body response to degradation, fraying, or particle loss. Dr. Klinge acknowledges in his report that all surgical mesh products "cause an initial and chronic inflammatory tissue response in the patient after implantation." *See* Ex. B, Klinge PROLENE* Report at 7.

In other words, the symptoms Dr. Klinge describes—inflammation and chronic foreign body response—are present regardless of the material that is used. Dr. Klinge has done nothing to exclude the possibility that the inflammation he believes is the result of degradation, fraying, and particle loss is not actually the normal and anticipated reaction following the implantation of any foreign body. More simply, he has failed to rule out an alternative cause.

II. The Court Should Limit Certain of Dr. Klinge's Opinions Regarding PROLENE* Soft.

a. The Court should once again exclude any testimony from Dr. Klinge regarding alternative designs to PROLENE* Soft.

On page 16 of his PROLENE* Soft report, Dr. Klinge states, "The PVDF product, Dynamesh, is a safer design than Gynemesh PS [i.e., PROLENE* Soft Mesh] for all of the reasons stated above as further established in Muehl's testing." *See* Ex. C, Klinge PROLENE*

Soft Report at 16. This statement is the first reference to polyvinylidene fluoride, or PVDF, in the report, and Dr. Klinge cites no literature or other reliable, objective data to support it. In fact, the only other references to PVDF—or any other alternative design, for that matter—in Dr. Klinge's entire report are summaries of company documents that, in Dr. Klinge's view, show Ethicon considered PVDF as an alternative to polypropylene, among other possible changes to the design of PROLENE* Soft Mesh. *See* Ex. C, Klinge PROLENE* Soft Report at 25–26.

Notably, Dr. Klinge's PROLENE* Soft report is virtually identical to the report he submitted in *Bellew*, where this Court excluded Dr. Klinge's opinions on alternative design. The Court found that, in the section of his *Bellew* report addressing alternative design, "Dr. Klinge fails to cite *any* peer-reviewed studies." Mem. Op. & Order (*Daubert* Motions) at 16, *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473 (S.D. W. Va. Nov. 20, 2014). This Court also emphasized that "Dr. Klinge's report provides no indication that his alternative design opinions are based on anything other than his and Dr. Mühl's effective porosity testing and internal Ethicon documents," which the Court deemed "not sufficiently reliable scientific bases under *Daubert*." *Id.* Because Dr. Klinge has submitted the same report here, the Court should again exclude his alternative design opinions.

The plaintiffs here may well argue that a different result is compelled by Dr. Klinge's *de bene esse* deposition in *Bellew*—which occurred after *Daubert* briefing in *Bellew* but before the Court issued its opinion excluding Dr. Klinge's alternative design opinions. Any such argument would be misplaced. Dr. Klinge testified in *Bellew* that he is not aware of any peer-reviewed studies showing PVDF—or any other proposed alternative to PROLENE* Soft—is safer and more effective at treating pelvic organ prolapse. *See* Ex. G, Klinge 11/10/14 Dep. Tr. 182:14–184:2 (testifying he is not aware of any clinical studies showing alternative mesh design that has

lower rate of erosion, that causes less chronic pain, or that has lower contracture rate than PROLENE* Soft Mesh).

In fact, when Dr. Klinge was asked in that deposition whether he could even identify "any mesh . . . that's appropriate for use in the pelvic floor for the repair of pelvic organ prolapse," Dr. Klinge responded, "I cannot give a general statement to this. I know that there are textile constructions and design for meshes that are more resistant to the [pore] collapse, but it depends on the indication of the specific situation." *Id.* at 163:8–15.

Dr. Klinge later confirmed that he could not name one mesh with usage benefits that exceed the risks of use in the treatment of pelvic organ prolapse. *Id.* at 184:3–6. And he specifically denied that a larger-pore mesh like Ultrapro is a safer alternative to PROLENE* Soft. *Id.* at 90:11–20 ("Ultrapro obviously does not prevent a pore collapse when applied to forces; therefore, it is not the best idea to use Ultrapro in this – for this indication, yes.").

In short, nowhere in his Rule 26 expert report or in his *de bene esse* deposition does Dr. Klinge cite peer-reviewed literature to support his opinion that PVDF or mesh with larger pores were safer alternatives to PROLENE* Soft. Instead, he relies only on his "effective porosity testing and internal Ethicon documents, which are not sufficiently reliable scientific bases under *Daubert*." Mem. Op. & Order at 16, *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473. As a result, he should not be permitted to testify at trial regarding alternative designs.[1]

b. Dr. Klinge's opinions regarding fraying and particle loss in PROLENE* Soft should be excluded.

The Court should also exclude Dr. Klinge's opinion that PROLENE* Soft is defective because it is subject to fraying and particle loss. *See* Ex. C, Klinge PROLENE* Soft Report at

[1] Dr. Klinge should also be precluded from testifying about PVDF as an alternative to PROLENE* Soft because PVDF has not been approved by the FDA, is more expensive, and is more difficult to handle. *See supra* Section I.a.

19–23. In support of that opinion, Dr. Klinge cites a number of Ethicon documents relating to TVT, a mid-urethral sling used in the treatment of stress urinary incontinence, not pelvic organ prolapse. For example, Dr. Klinge cites a 2003 memorandum to the TVT file indicating that "fraying is inherent in the design and construction of the product," clinical reports from 2004 describing "crumbling" of TVT, and elongation studies comparing the effect of various methods of cutting TVT mesh. *Id.* at 19–20. Dr. Klinge also relies on a 2003 study by Pariente describing "particle shedding" in TVT. *Id.* at 20.

The Ethicon documents and the Pariente study cited by Dr. Klinge provide no support whatsoever for his opinion that PROLENE* Soft Mesh frays and loses particles. Ethicon uses PROLENE* Mesh in the TVT device described in these documents, not the PROLENE* Soft Mesh found in Prolift and Ethicon's other pelvic organ prolapse products. As mentioned, PROLENE* and PROLENE* Soft have different designs, including different pore sizes and different weights (PROLENE* Soft has larger pores and weighs less). Thus, even if internal company documents were somehow a reliable basis to show mesh fraying and particle loss in PROLENE*, these internal documents cannot reliably support Dr. Klinge's opinion that PROLENE* Soft Mesh frays and loses particles, insofar as the documents relate to an entirely different product.

Stripped of the TVT documents, the only "data" Dr. Klinge cites in support of his opinion that PROLENE* Soft Mesh frays and loses particles is his observation of "curled and roped mesh . . . in the Prolift implantation videos" he was provided. *See* Ex. C, Klinge PROLENE* Soft Report at 23. In his *de bene esse* deposition for *Bellew*, Dr. Klinge referenced this same video, again identifying it as proof of roped and curled mesh. *See* Ex. G, Klinge 11/10/14 Dep. Tr. 73:7–75:18. Nowhere in his report or in his deposition, however, does Dr. Klinge explain

how mesh roping or curling allegedly seen in this video is related to his claim that PROLENE* Soft Mesh frays and loses particles. Without a reliable basis to support his opinion that fraying and particle loss occur, Dr. Klinge should not be permitted to testify about this supposed defect.

Dr. Klinge is also unable to explain the clinical significance, if any, of fraying and particle loss. In his report, Dr. Klinge opines that, "more probably than not, particulates scattered throughout the pelvic tissue will create an inflammatory response of some magnitude; will increase the overall foreign body reaction and inflammatory response; will increase the amount of the fibrotic reaction; and will run the risk of migrating into other parts of the body." *See* Ex. C, Klinge Prolene Soft Report at 23. Dr. Klinge cites no peer-reviewed literature for this opinion, and he has previously testified that he does not know of "any clinical study testing the relationship between particle loss and the clinical outcome." *See* Ex. E, Klinge 11/15/13 Dep. Tr. 411:12–24. For all of these reasons, the Court should preclude Dr. Klinge from offering opinions at trial regarding mesh fraying and particle loss.[2]

c. Dr. Klinge has no reliable basis to testify about the significance of alleged degradation of PROLENE* Soft.

Dr. Klinge's opinion that PROLENE* Soft Mesh degrades also fails to withstand scrutiny under *Daubert*. *See* Ex. C, Klinge PROLENE* Soft Report at 17–19. In his report, Dr. Klinge describes articles by Costello, Clave, and others that purportedly demonstrate the degradation of polypropylene when implanted in the human body. *Id.* at 17. But Dr. Klinge cites no peer-reviewed literature in support of his bald assertion that degradation of polypropylene can create an enhanced inflammatory tissue response. *See id.* at 18.

[2] Dr. Klinge's opinions about degradation and fraying of PROLENE* Soft are also irrelevant, insofar as the plaintiffs cannot show that their PROLENE* Soft degraded or frayed while implanted. *See supra* Section I.b.

Dr. Klinge was not asked about degradation during his *de bene esse* deposition in *Bellew*, so plaintiffs here cannot rely on his testimony to fill the gaps of his expert report. In prior depositions, however, Dr. Klinge was questioned extensively about degradation, and he acknowledged that he is not aware of a single clinical study to address the implications of polypropylene degradation. *See* Ex. E, Klinge 11/15/13 Dep. Tr. 516:1–9 ("I don't know any study that was able to differentiate whether [clinical manifestations resulted from] surface cracking, whether it was a surface of the material, whether it was the functional biocompatibility of the device, therefore.").

Dr. Klinge further acknowledged that, without any data or clinical studies, he is unable to tie degradation to any specific complication. *Id.* at 511:1–19 ("My current opinion to this point is that at the moment we don't have sufficient data to quantify exactly the consequence of this finding [of degradation] to the clinical outcome."); *see also* Ex. H, Klinge 10/23/12 Dep. Tr. 416:21–25 ("But today it is right that in the moment, we don't have a full understanding what is clinical relevance [of degradation]. It would be too rough to correlate this surface cracking to some specific complication there."). Dr. Klinge therefore cannot reliably opine that degradation of PROLENE* Soft is clinically significant, and his opinions about degradation should be excluded.

d. Dr. Klinge should not be permitted to testify in cases involving Prolift+M.

Finally, Dr. Klinge has been disclosed as a general expert witness in two cases—*Freeman v. Ethicon*, No. 2:12-cv-00490 and *Walker v. Ethicon*, No. 2:12-cv-00873—that involve Prolift+M. Like Gynemesh PS, Prolift, and Prosima, Prolift+M was manufactured by Ethicon for the treatment of pelvic organ prolapse. Unlike these other devices, however, Prolift+M uses a partially absorbable mesh that results in larger pores and less weight than the PROLENE* Soft Mesh at issue in Dr. Klinge's report.

Nowhere in his report does Dr. Klinge offer any opinions about the mesh used in Prolift+M. In fact, in an effort to show Ethicon allegedly investigated problems with PROLENE* Soft Mesh, Dr. Klinge discusses a number of company documents in which Ethicon considered using Ultrapro mesh, which is the same mesh eventually used in Prolift+M.

Because Dr. Klinge's report does not include any opinions regarding the Prolift+M, he should be excluded as an expert witness in the Wave 1 cases involving Prolift+M — *Freeman* and *Walker*.

III. Dr. Klinge's Narrative Summary of Ethicon Documents and Depositions and His Opinions Concerning Ethicon's Knowledge, State of Mind, and Corporate Conduct Should Be Excluded.

Both of Dr. Klinge's expert reports are replete with opinions regarding Ethicon's alleged knowledge of a variety of topics and narrative summaries of Ethicon's documents. *See, e.g.*, Ex. B, Klinge PROLENE* Report at 9 ("Ethicon employees have testified that Ethicon knew before the launch of its pelvic meshes . . . that in some women, there would be a severe FBR . . . ."); *id.* at 14 ("Numerous Ethicon internal documents demonstrate Ethicon was acutely aware of the heavyweight, small pore problem."); Ex. C, Klinge PROLENE* Soft Report at 29 ("According to their documents, Ethicon also acknowledged why these design requirements were so important in terms of patient safety."); *id.* (". . . Ethicon knew that poor design leads to poor outcome."). This Court ruled in *Lewis* that Dr. Klinge's opinions regarding Ethicon's documents and corporate knowledge "are not appropriate subjects of expert testimony because opinions on these matters will not assist the jury." *Lewis v. Ethicon, Inc.*, No. 2:12-cv-4301, 2014 WL 186872, at *5 (S.D. W. Va. Jan. 15, 2014).

In the *Bellew* case, Dr. Klinge included in his report the same improper opinions regarding Ethicon's knowledge and state of mind. In response to Ethicon's *Daubert* motion, the

plaintiff insisted she did not intend to elicit such testimony from Dr. Klinge, and the Court denied as moot Ethicon's motion on this point. *See* Mem. Op. & Order at 14-15, *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473 (S.D. W. Va. Nov. 20, 2014).

Yet, during Dr. Klinge's *de bene esse* deposition for *Bellew*, the plaintiff's counsel elicited the very testimony Ethicon had moved to exclude. *See, e.g.*, Ex. G, Klinge 11/10/14 Dep. Tr. 65:23–66:4 ("Q. Okay. In your review of the internal Ethicon documents in this case, did you determine whether Ethicon's scientists had considered your and Dr. Mühl's pore testing publications and the effects of mesh pore size under strain? A. Yes I did."); *id.* at 67:7–10 ("They are circulating our manuscript that we published in 2005 as a sophisticated method to measure porosity, so they have been aware of it."). Counsel for the plaintiffs elicited the same type of testimony in Dr. Klinge's *de bene esse* deposition for the *Mullins* consolidated case. *See, e.g.*, Ex. F, Klinge 11/4/15 Dep. Tr. 24:1–18 (testifying that "internal Ethicon document" "clearly expressed that . . . the Ethicon scientists still recognized the importance of, first, large pore sizes and, second, minimal amount of foreign body material as recommendations for a mesh construction.").

As this Court has already recognized, Dr. Klinge's opinions about Ethicon's knowledge and corporate conduct should be excluded. These opinions would not be helpful to the jury, *see Lewis*, 2014 WL 186872, at *6, and they "would actually invade the province of the jury rather than assist it in resolving material issues of fact" insofar as the opinions are predicated on nothing more than Dr. Klinge's own reading of Ethicon's documents. *See Hines v. Wyeth*, No. 2:0v-0690, 2011 WL 2680842, at *7 (S.D. W. Va. July 8, 2011).

IV. If Reached, Dr. Klinge Should Be Precluded From Offering Opinions or Testimony Based on PROLENE* Polypropylene Sutures.

As stated above, Dr. Klinge has no testing or literature to support the proposition that PROLENE* degrades in the body in any clinically significant way.

However, if he is allowed to testify about degradation, he should either not be allowed to use Ethicon's suture studies to support his opinion or Ethicon should be allowed to impeach him with evidence of the FDA's approval of sutures for implantation in the human body.

Dr. Klinge's opinions that polypropylene mesh degrades *in vivo* and that PVDF mesh is, for that reason, a safer alternative to polypropylene mesh are based in part on Ethicon's "7-year dog study." *See* Ex. B, Klinge PROLENE* Report at 38; Ex. C, Klinge PROLENE* Soft Report at 19. That study, Dr. Klinge claims, demonstrated that Ethicon's PROLENE* sutures are subject to "progressive degradation," whereas PVDF sutures are not. *Id.* Dr. Klinge extrapolates from this study to conclude that PROLENE* and PROLENE* Soft also degrade.

Even if permitted to testify about polypropylene degradation and the availability of PVDF mesh as an alternative, Dr. Klinge should not be able to offer opinions regarding PROLENE* polypropylene sutures. Any such opinion would be preempted by federal law.

A PROLENE* polypropylene suture is a medical device specifically approved and regulated by the FDA pursuant to the New Drug Application ("NDA") process. As the Court is aware, the FDA approved PROLENE* polypropylene sutures as an implantable medical device when it approved the PROLENE* polypropylene suture NDA in 1969. *See, e.g.*, Mem. Supp. Mot. Partial Summ. Judg. Based on Preemption at 2–4, *Lewis v. Johnson & Johnson*, No. 2:12-cv-04301 (S.D. W. Va. Dec. 12, 2013), ECF No. 129. From 1976 to 1990, the FDA regulated PROLENE* sutures as a Class III medical device subject to the Premarket Approval (PMA) process. *See id.* at 4. In 1988, the FDA approved labeling that said PROLENE* was not "subject

to degradation or weakening by action of the tissue enzymes." *Id.* In 1990, the FDA reclassified PROLENE* and other polypropylene sutures as a Class II device, subject to less rigorous controls, based on the proven safety and effectiveness of polypropylene sutures. *See id.* at 4–5.

As the Court has recognized, the FDA's Premarket Approval review is much more rigorous than the 510(k) process, and design defect claims for PMA-approved devices are typically preempted. *See, e.g., Lewis v. Johnson & Johnson*, 991 F. Supp. 2d 748, 751–52 (S.D. W. Va. 2014) (discussing differences between PMA and 510(k) processes and acknowledging that "tort claims regarding medical devices approved through the premarket approval process generally are preempted"). Thus, if the plaintiffs were suing for alleged design defects in PROLENE* sutures, their claims would be preempted in light of the FDA's approval of these devices. For that reason, Dr. Klinge should not be allowed to rest his opinions on suture studies.

In the alternative, Ethicon should be allowed to impeach any such testimony with proof of FDA approval. In prior cases in this MDL, the Court has consistently excluded evidence of FDA actions, including the FDA's approval and reclassification of PROLENE* sutures. Assuming the Court follows that approach in this case, Ethicon will be unduly prejudiced by any testimony from Dr. Klinge concerning or relying upon the alleged *in vivo* degradation of PROLENE* or polypropylene sutures. If this testimony is not excluded, Dr. Klinge would be free to testify that PROLENE* sutures degrade *in vivo*, but Ethicon would be unable to rebut this opinion with evidence that the FDA did not find degradation, if any, to be clinically significant and approved PROLENE* and other polypropylene sutures to be safe and effective for use in the human body.

V. If Reached, the Court Should Exclude Dr. Klinge's Opinions Regarding Effective Porosity.

As discussed above, Dr. Klinge cannot identify a safer and equally effective alternative design. Because of that, any views he might have that a larger pore mesh might be safer is irrelevant to this case, and his views about "effective porosity" would unfairly prejudice Ethicon and confuse the jury. The size of the pores is only relevant if larger pores would work better, and without a safer alternative design any such testimony is purely speculative.

Dr. Klinge describes at length in his reports his collaboration with Dr. Thomas Mühl, with whom Dr. Klinge developed the novel concept of "effective porosity." According to Dr. Klinge, effective porosity is, with respect to polypropylene mesh, a measurement of "only those pores and those parts of the pores . . . which have dimensions greater than 1 mm or 1000 μm in all directions." *See* Ex. B, Klinge PROLENE* Report at 16. Drs. Klinge and Mühl also attempted to measure how the effective porosity of mesh changes when the mesh is placed under strain, a concept they refer to as "effective porosity under strain." *Id.* Based on testing devised by Dr. Mühl, Dr. Klinge opines that PROLENE* and PROLENE* Soft have insufficient effective porosity and effective porosity under strain. *Id.* at 21.

The plaintiffs in Wave 1 have also disclosed Dr. Mühl as an expert witness, and Ethicon has moved to exclude his opinions as unreliable. Ethicon hereby incorporates by reference its motion to exclude Dr. Mühl and the memorandum supporting the same. For the same reasons set forth in that motion and memorandum, Dr. Klinge should be precluded from testifying regarding the effective porosity and effective porosity under strain of PROLENE* and PROLENE* Soft.

CONCLUSION

For the reasons set forth above, certain of Dr. Klinge's opinions fail to pass muster under *Daubert*, and the Court should limit his testimony at trial.

Respectfully submitted,

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IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	**Master File No. 2:12-MD-02327** **MDL 2327**
THIS DOCUMENT RELATES TO: **WAVE 1 CASES**	**JOSEPH R. GOODWIN** **U.S. DISTRICT JUDGE**

CERTIFICATE OF SERVICE

I hereby certify that on April 20, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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